



EU Quality Assurance Certificate Regulation (EU) 2017/745, Annex XI Part A

MDR 768587 R000

Manufacturer: Medline International France SAS

Address: 5, rue Charles Lindbergh Chateaubriant 44110 France Single Registration Number: FR-MF-000000676

Scope: See attached Device Schedule

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex XI part A, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb devices an additional Annex X certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: 2023-05-10

Current Issue Date: 2024-07-03

Starting Validity Date: **2024-07-03** Expiry Date: **2028-05-09** ...making excellence a habit."

Page 1 of 3

Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80 Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK. A Member of the BSI Group of Companies.





EU Quality Assurance Certificate Regulation (EU) 2017/745, Annex XI Part A

MDR 768587 R000

Device Schedule: Class IIa, Custom-made and other devices

| Device(s) | Risk Classification | | 1 |
|--|--|---------|--------|
| Wound Protector Drape | Class IIa | | 1222 |
| Suture Boots | Class IIa | | |
| Surgical Gowns | Class Is | | Linde |
| Surgical Drapes, Drape packs and accessories | Class Is | | 7.82 |
| Equipment and Instrument Covers | Class Is | VICh | |
| Plastic Bone Cement Mixing with Spatulas | Class Is | | 40000 |
| Plastic Cautery Holsters | Class Is | No. No. | 1 |
| Patient Plastic Devices and sets (Cups and lids, bowls and | Class Is | 1 122 | |
| lids, basins and lids, trays and pitchers) | | | |
| Table Cover | Class Is | | |
| Surgical Skin Marker and Ruler | Class Is | 00 | 21. 15 |
| Suction tubing and accessories | Class Is | | 1957 |
| Instrument Pad | Class Is | 21 | |
| Securement Dressing | Class Is | | |
| For Class Tanda inc. He Net/God Dada and Camilla and a | the Bartha different a second and a latter of a second | 1 | |

For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions.

First Issue Date: 2023-05-10

Current Issue Date: 2024-07-03

Starting Validity Date: **2024-07-03** Expiry Date: **2028-05-09** ...making excellence a habit."

Page 2 of 3

Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80 Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK. A Member of the BSI Group of Companies.





EU Quality Assurance Certificate

Regulation (EU) 2017/745, Annex XI Part A

MDR 768587 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

| Date | Reference Number | Action | |
|------------|------------------|--|--|
| 2023-05-10 | 3655293 | Issued | |
| 2023-11-28 | 30050666 | Amended - Addition of subcontract manufacturer and sterilization service provider for Class Is Securement Dressing Amended - Removal of sterilization service provider for surgical drapes and gown packs Supplemented - Addition of Class Is Securement Dressing | |
| 2024-04-04 | 30124632 | Supplemented - Addition of Class IIa Suture Boots device Amended - Addition of subcontractor manufacturing location for Class Is surgical drapes, gowns and drape packs | |
| Current | 30209651 | Amended - Addition of ethylene oxide sterilization subcontractor | |

First Issue Date: 2023-05-10

Current Issue Date: 2024-07-03

Starting Validity Date: **2024-07-03** Expiry Date: **2028-05-09** ...making excellence a habit."

Page 3 of 3

Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80 Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK. A Member of the BSI Group of Companies.